

Remarks

The Office Action mailed April 29, 2004 has been received and reviewed. Claims 5, 10, 12, and 36 having been canceled, and claims 20, 27, 29, 34, and 37-39 having been amended, the pending claims are claims 1-4, 6-9, 11, 13-35, and 37-39. Reconsideration and withdrawal of the rejections are respectfully requested.

Double Patenting Rejection

Claims 1-4, 6-9, 11, 13-35, and 37-39 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,500,798. Claims 1-4, 6-9, 11, 13-35, and 27-39 were also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent Application Serial No. 09/641,802. Submitted herewith is a Terminal Disclaimer which, Applicants submit, is in compliance with 37 CFR 1.321(c) and thereby obviates the Examiner's double patenting rejection of claims 1-4, 6-9, 11, 13-35, and 37-39

Claim Objection

In view of the amendment of claim 20 to recite "selected from the group consisting of," Applicants respectfully submit that the Examiner's objection to claim 20 is moot.

The 35 U.S.C. §102 Rejection

The Examiner rejected claims 20-35 under 35 U.S.C. §102(b) as being anticipated by Janusz et al. (*Molecular Immunology*; 24(10):1029-1031). The Examiner also rejected claims 20-35 under 35 U.S.C. §102(b) as being anticipated by Inglot et al. (*Archivum Immun Thera Exp*; 44(4):215-224). Applicants traverse the rejection of claims 20-35 as being anticipated by either Janusz et al. or Inglot et al. According to MPEP § 2131 a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Applicants respectfully submit that neither Janusz et al. nor Inglot et al. set forth each and every element of the methods of claims 20-35. Janusz et al. teaches that the administration of the colostrinin nonapeptide NP (SEQ ID NO:31) to mice enhances the primary immune response to sheep red blood cells (SRBC) in the mice (Janusz et al., page 1030). Inglot et al. teaches that colostrinin is a "modest inducer" of the cytokines IFN and TNF in human peripheral blood leukocytes and whole blood cultures and resulted in "psycho-stimulation" when orally administered to two human patients (see Inglot et al., abstract and page 215).

Claims 20-28 are drawn to "[a] method for modulating leukocyte proliferation, the method comprising contacting leukocytes with a leukocyte regulator . . . under conditions effective to change the number of leukocytes . . . wherein the number of leukocytes is changed," while claims 29-35 are drawn to "[a] method for modulating leukocyte proliferation in a patient, the method comprising administering to the patient a leukocyte regulator . . . under conditions effective to change the number of leukocytes . . . wherein the number of leukocytes is changed." In the claimed methods for modulating leukocyte proliferation, leukocytes are contacted with a leukocyte regulator (claims 20-28) or a leukocyte regulator is administered to a patient (claims 29-35) "under conditions effective to change the number of leukocytes . . . wherein the number of leukocytes is changed." Thus, in the claimed methods a leukocyte regulator is administered *under conditions effective to change the number of leukocytes, and wherein the number of leukocytes is changed*. Applicants respectfully submit that the Examiner's statements that claims 20-35 "are drawn to a method which comprises the step of contacting cells with an 'immunological regulator'" and that "[n]o other limitations are present in the claims" (pages 4 and 6 of the Office Action mailed April 29, 2004) are incorrect.

Applicants submit that neither Janusz et al. nor Inglot et al. teach administering a leukocyte regulator *under conditions effective to change the number of leukocytes or wherein the number of leukocytes is changed*. Thus, the disclosures of Janusz et al. or Inglot et al. do not set forth each and every element of claims 20-35. Withdrawal of this rejection under 35 U.S.C. §102(b) is respectfully requested.

Amendment and Response

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Serial No.: 09/641,801

Confirmation No.: 5388

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For: USE OF COLOSTRININ, CONSTITUENT PEPTIDES THEREOF, AND ANALOGS THEREOF FOR INDUCING CYTOKINES

Summary

It is respectfully submitted that the pending claims 1-4, 6-9, 11, 13-35, and 37-39 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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CERTIFICATE UNDER 37 CFR §1.10:

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The undersigned hereby certifies that the Transmittal Letter and the paper(s) and/or fee(s), as described hereinabove, are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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